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PATENT APPLICATION TRANSMITTAL LETTER
(Small Entity)

Docket No.
MED-02702/29

TO THE ASSISTANT COMMISSIONER FOR PATENTS

jc135 U.S. PTO 09/523503 03/10/00

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

Michael A. Masini

For: **OPTIMIZING PATELLAR FEMORAL MECHANICS THROUGH ALTERNATIVE DEPTH REFERENCING**

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. EK597673434US
- ☒ Five (5) sheets of drawings.
- ☐ A certified copy of a application.
- ☒ Declaration ☒ Signed. ☐ Unsigned.
- ☒ Power of Attorney
- ☐ Information Disclosure Statement
- ☐ Preliminary Amendment
- ☒ Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
- ☐ Other:

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	15	- 20 =	0	x $9.00	$0.00
Indep. Claims	5	- 3 =	2	x $39.00	$78.00
Multiple Dependent Claims (check if applicable) ☐					$0.00
				BASIC FEE	$345.00
				TOTAL FILING FEE	$423.00

- ☒ A check in the amount of $423.00 to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **07-1180** as described below. A duplicate copy of this sheet is enclosed.
  - ☐ Charge the amount of as filing fee.
  - ☒ Credit any overpayment.
  - ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
  - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **March 10, 2000**

Signature

John G. Posa
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Gifford, Krass, Groh et al
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cc:

PATENT

IN THE UNITED PATENT AND TRADEMARK OFFICE

Attorney's Docket No.: MED-02702/29

■ In re application of: Masini

Serial No.: Group No.:

Filed: Examiner:

For: OPTIMIZING PATELLAR FEMORAL MECHANICS THROUGH ALTERNATIVE DEPTH REFERENCING

☐ Patent No.: Issued:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(c-f) and 1.27(b-d))

With respect to the invention described in

■ the specification filed herewith.
☐ application Serial No. _____, filed _____.
☐ patent no. _____, issued _____.

I. IDENTIFICATION OF DECLARANT AND RIGHTS AS A SMALL ENTITY

I hereby declare that I am

(a) Independent Inventor

☐ a below named independent inventor and that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code to the Patent and Trademark Office.

(b) Non-inventor Supporting a Claim by Author

☐ making this verified statement to support a claim by _____ for a small entity status for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code and I hereby declare that I would qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, I had made the above identified invention.

(c) Small Business Concern

☐ the owner of the small business concern identified below.
■ an official of the small business concern empowered to act on behalf of the concerned identified below.

NAME OF CONCERN MedIdea, LLC
ADDRESS OF CONCERN 1204 Harbrooke Ave.
Ann Arbor, MI 48103

and that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees

of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

(d) Non-Profit Organization

☐ an official empowered to act on behalf of the non-profit organization identified below:

NAME OF CONCERN _____
ADDRESS OF CONCERN _____
_____

TYPE OF ORGANIZATION

☐ UNIVERSITY OR OTHER INSTITUTE OF HIGHER EDUCATION
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3))
☐ NON-PROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NON-PROFIT SCIENTIFIC OR EDUCATION UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

and that the non-profit organization identified above qualifies as a non-profit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code.

II. OWNERSHIP OF INVENTION BY DECLARANT

I hereby declare that rights under contract or law remain with and/or have been conveyed to the above identified

☐ person	■ concern	☐ organization
(item (a) or (b) above)	(item (c) above)	item (d) above)

EXCEPT, that if the rights held are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held (1) by any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, (2) any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or (3) a non-profit organization under 37 CFR 1.9(e).

☐ no such person, concern, or organization
■ person, concerns or organizations listed below*

**NOTE Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)*

FULL NAME _____
ADDRESS _____
_____
☐ Individual ☐ Small Business Concern ☐ Non-Profit Organization

FULL NAME _____
ADDRESS _____
_____
☐ Individual ☐ Small Business Concern ☐ Non-Profit Organization

III. ACKNOWLEDGEMENT OF DUTY TO NOTIFY PTO OF STATUS CHANGE

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

IV. DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

V. SIGNATURES

(complete only (e) or (f) below)

(e)

NOTE: All inventors must sign the verified statement

_____
Name of Inventor

_____ Date _____
Signature of Inventor

_____
Name of Inventor

_____ Date _____
Signature of Inventor

OR

(f)

NOTE. The title of the person signing on behalf of a concern or non-profit organization should be specified

NAME OF PERSON SIGNING John G. Posa

TITLE OF PERSON SIGNING Member

ADDRESS OF PERSON SIGNING 1204 Harbrooke Ave.

Ann Arbor, MI 48104

SIGNATURE _____ DATE 3/10/00

MED-02702/29
00903sh

OPTIMIZING PATELLAR FEMORAL MECHANICS THROUGH ALTERNATIVE DEPTH REFERENCING

Reference to Related Application

This application claims priority of U.S. provisional application Serial No. 60/120,062, filed March 12, 1999, the entire contents of which is incorporated herein by reference.

Field of the Invention

This invention relates generally to orthopedic surgery and, in particular, to alternative depth referencing in conjunction with knee-replacement surgery.

Background of the Invention

Whether for primary or revision arthroplasty, cutting guides are typically employed to ensure that the bone saw performs resections corresponding to mating surfaces of the prosthetic component. For example, in a femoral knee replacement, cutting guides or blocks are temporarily secured to the distal end of the femoral shaft, and include slots into which the blade of an oscillating saw is inserted to shape the end of the bone in accordance with corresponding surfaces of the prosthetic element.

The distal end portion of a natural femur terminates in two bulbous protrusions termed the medial and lateral condyles, which mate and engage with corresponding surfaces in the proximal end of the tibia. As a result of disease or injury, these mating surfaces, ordinarily smooth and cushioned by an intervening cartilage layer, disintegrate and/or become misshapen, resulting in restricted movement and pain.

To ameliorate these conditions, the orthopedic surgeon removes the unhealthy bone stock and replaces it with one or more metallic components which adhere to appropriately prepared bone surfaces and approximate the outer, cortical layer of a healthy bone. To prepare the existing damaged or diseased bone to accept the implant components, various resections are made in a predetermined manner in correspondence with the inner surfaces of the implant.

Using the example of a distal femur, a saw guide is used to form resected surfaces typically including a distal cut, anterior and posterior cuts, and perhaps anterior or posterior chamfer cuts. Although these cuts represent resections made in conjunction with a standard implant technique, more, fewer or different surfaces may be required, depending upon the level of deterioration or other circumstances.

Depending upon the saw guide used, either the cuts associated with only one of the condyles may be resected, or, alternatively, a guide having a dual set of slots may be utilized to trim both condyles simultaneously. A singular type fixture is shown, for example, in U.S. Pat. No. 5,122,144, whereas guides having double sets of slots are shown in U.S. Pat. Nos. 5,129,909 and 5,364,401. Numerous other examples are evident in the prior art, some of which are in commercial usage.

Certain problems may arise in making the aforementioned resections, particularly with respect to placement of the distal cut in conjunction with total knee arthroplasty. A distal femur usually exhibits about seven degrees of valgus for a man, and about nine degrees of valgus for a woman. The corresponding tibia usually requires three degrees of

varus. As a consequence, the total alignment for a man is about four degrees of valgus, whereas the alignment for a woman is about six degrees of valgus.

One problem arises from the fact that placement of the distal cutting guide is usually based on the most prominent condyle, which tends to be the medial condyle. Since the proximal tibia is typically removed as part of a joint replacement, more bone is ordinarily removed laterally as compared to medially, so that the resulting configuration is no longer varus, but neutral, or zero degrees. This means that relative to the femur, more bone must be removed medially than laterally. This situation has implications to the flexion and extension gaps relative to the patella femoral joint.

Reference is made to Figure 1, which is an anterior-posterior view of a distal femur, depicted generally at 100, with the medial femoral condyle being shown at 102. The instrumentation associated with current procedures includes an intramedullary rod 103 on which there is mounted distal plate 104. Once plate 104 contacts the distal femur, it is set into place. Then a distal cutting guide 202 having one or more slots is positioned relative to the plate on a plate extension 203 which typically includes markings enabling the surgeon to determine how much bone will be removed. The distal cutting guide slides in a distal-to-proximal direction on 203 until a desired depth is selected. Figure 2 is a lateral view of the same device 203 viewed from an oblique perspective showing the extension arm on which the cutting guide 202 can slide proximal to distal. Item 201 is the intramedullary rod.

In any case, since the plate rests against the most proud condyle, the chosen level will lead to more resection from the medial side and less from the lateral side.

Depending upon patient anatomy, additional bone may or may not be removed from the region of the trochlea, which is the central depression between the two distal portions.

Figure 3A shows the expected result without instrumentation in the AP plane, that is, how more of the proximal tibia will be trimmed laterally than medially, and how, correspondingly, more of the distal femur will be resected medially than laterally, so as to create a symmetric extension gap. Figure 3B is a drawing which helps to understand the problems caused by the goal of a symmetric extension gap. A distal advancement of the lateral condyle is evident, which is shown between the two arrows. This also results in a distal advancement of the trochlea, depending on the size of the patient.

Figure 4 represents the effect this approach has on the extensor mechanism with the patella intact. In essence, the extensor mechanism is displaced more distally with respect to the patella. The increased moment arm of the extensor mechanism results in increased force on the patella in flexion, increased potential for wear, loss of flexion of the joint, and altered tracking of the patella (i.e., patella tilt).

Summary of the Invention

In knee-replacement surgery, the present invention allows for the creation of a symmetric extension gap while providing restoration of the joint line with respect to patellar femoral joint in the distal plane, thereby optimizing patellar femoral mechanics. Broadly, in meeting this objective, the depth of the trochlea is increased with increasing implant size. In the preferred embodiment, this is achieved by referencing the extent of the lateral femoral condyle or trochlear region, and resecting the distal femur in

accordance with the extent of the lateral femoral condyle or trochlear region. As an alternative, the invention provides for distal femoral and proximal tibial components having bone-contacting and articulating surfaces which account for the measured extent of the lateral femoral condyle or trochlear region.

A method of preparing a distal femur according to the invention includes the steps of installing a rod or stem within the intramedullary canal, and attaching a referencing fixture thereto. The extent of the lateral femoral condyle or trochlear region is measured using the referencing fixture, and the distal femur is resected in accordance with the extent of the lateral femoral condyle or trochlear region. The method typically further includes the step of placing a spacer between the referencing fixture and the lateral femoral condyle or trochlear region. The preferred alternative embodiment of the invention involving the use of modified components proceeds similarly, except that after measuring the extent of the lateral femoral condyle or trochlear region using the referencing fixture, distal femoral and proximal tibial components are implanted having bone-contacting and articulating surfaces which take the measurement into account.

Brief Description of the Drawings

FIGURE 1 is an anterior-posterior view of a distal femur including an intramedullary rod on which there is mounted a prior-art distal plate used for depth referencing;

FIGURE 2 is a lateral view of the device of Figure 1 viewed from an oblique perspective showing an extension arm on which a cutting guide can slide proximal to distal;

FIGURE 3A shows how the proximal tibia is trimmed more laterally than medially according to current techniques;

FIGURE 3B is a drawing which helps to understand the problems caused by the use of the medial condyle as the reference for the distal resection;

FIGURE 4 represents the effect of a symmetric extension gap on the extensor mechanism with the patella intact;

FIGURE 5 illustrates a distal cutting guide according to the invention which references the lateral femoral condyle as opposed to the medial condyle;

FIGURE 6 is a drawing that illustrates an alternative embodiment wherein an appropriately shaped spacer is placed in the region of the trochlea so as to perform the distal resection relative to the trochlea;

FIGURE 7 shows how a final implant may be modified as opposed altered resections according to the invention;

FIGURE 8A shows how the thickness of a tibial implant may be made thicker while keeping the tibial insert symmetric;

FIGURE 8B shows how the thickness of a tibial spacer may be made thicker while keeping the implant or tray largely symmetric;

FIGURE 9A depicts the current situation involving symmetric medial and lateral condyles and the corresponding trochlea;

FIGURE 9B shows how, as implant size gets larger, the distance between the distal portions of both condyles and the trochlea increases by virtue of the invention; and

FIGURE 10 depicts an alternative embodiment of the invention includes a gauge moveable medially to laterally to reference either condyle or the trochlear region.

Detailed Description of the Invention

Having discussed the deficiencies of the prior art with reference to Figures 1 through 4, the reader's attention is now directed to Figure 5, which illustrates a distal cutting guide according to the invention which references the lateral femoral condyle as opposed to the medial condyle. In the event that the lateral femoral condyle is normally formed, a spacer 502 may be positioned between the extent of the lateral condyle and the distal plate, as shown. The amount of bone resected then would correspond to the difference between this point and the position of the cutting guide. If some bone loss were to occur laterally, this could be compensated through the use of a thicker spacer.

As an alternative, a preferred embodiment is seen in Figure 6, wherein an appropriately shaped spacer is placed in the region of the trochlea so as to perform the distal resection relative to the trochlea. In this manner, one would be sure that when one restored the ultimate final implant, that it was restored with respect to the patella femoral joint in the distal plane. The spacer 610 is used to reference the trochlea following osteophyte removal. Line 620 represents the level of resection to restore implant, bone construct to the level of the normal trochlea.

Figure 7 shows how one could actually alter the final implant as opposed to necessarily altering the cut. In this case, a distal position of the lateral femoral condyle would be less than the medial femoral condyle by an amount D. In addition, the trochlea would be deeper as well. A slight resection, of 10 millimeters, could be performed to that thickness of metal medially. Less metal would be restored laterally, on the order of 8 millimeters, for example, and the trochlea then correspond as well.

Using this approach, one would also have to make alterations to the tibial surface. This could be accomplished in several ways. One could have the metal thicker, as seen in Figure 8A, in which case the insert 802, typically polyethylene, would remain symmetric. Alternatively, the metal could be made symmetric, with the spacer also being made thicker by the distance D, as seen in Figure 8B. This would correct for any incongruity with respect to the extension gap, while still allowing for appropriate mechanics of the patella femoral joint.

By way of review, Figure 9A represents, once again, the current situation involving symmetric medial and lateral condyles and the corresponding trochlea. According to the invention, the trochlea depths, which are represented by D and D' prime would change for a given size. As such, when the size gets larger, such as size B in the drawing of Figure 9B, the distance between the distal portions of both condyles and the trochlea remains the same. However, according to the invention, as the size of implant increases, the depth of the trochlea increases correspondingly so as to optimize the patella femoral mechanics.

Figure 10 illustrates, from an oblique perspective, an embodiment of the invention including a medial-lateral slide enabling referencing to take place between either condyle or the trochlear region. The device includes a fixture 102 that rides on an intermedullary rod 104 including a groove 106 which receives a medial-lateral slide 110. The slide 110 further includes a slidable member 112, adjustable longitudinally in a manner generally parallel to the rod 104, including a referencing surface 114 and an angled member 116, including a cutting guide 120, which moves on the member 116, the member 116 further including calibrations 122 indicative of cutting depth. Note that the angled member 116 is not slidingly attached to the rod 112, but is rigidly attached thereto, such that as the assembly including rod and reference surface 114 moves longitudinally with respect to the bone, the member 116 moves therewith. In operation, the assembly containing rod 112, surface 114, member 116 and cutting block 120 may be moved medial to lateral, enabling the surface 114 to reference either condyle or the trochlear region of the bone 100. Having selected the reference point, the block 120 may be moved along member 116, taking note of the markings 122 which will be indicative of cutting depth. Upon selecting a desired cutting depth, one or more of the slots 124 may be used to resect either or both of the condyles, as the case may be.

I claim:

1. A method of installing a prosthesis onto a distal femur having an intramedullary canal so that the joint is restored with respect to the patellar femoral joint in the distal plane, the method comprising the steps of:

installing a rod or stem having a first end positioned within the intramedullary canal and a second end that remains exposed;

coupling a referencing fixture to the second end of the rod or stem;

measuring the extent of the lateral femoral condyle or trochlear region using the referencing fixture; and

installing the prosthesis in accordance with the extent of the lateral femoral condyle or trochlear region, as measured with the referencing fixture.

2. The method of claim 1, wherein the step of installing the prosthesis includes the step of resecting the distal femur in accordance with the extent of the lateral femoral condyle or trochlear region, as measured with the referencing fixture.

3. The method of claim 2, including the step of placing a spacer between the referencing fixture and the lateral femoral condyle or trochlear region.

4. The method of claim 1, wherein the step of installing the prosthesis includes the step of providing distal femoral and proximal tibial components having bone-contacting and articulating surfaces which account for the extent of the lateral femoral condyle or trochlear region, as measured with the referencing fixture.

5. A method of preparing a distal femur having an intramedullary canal for primary arthroplasty, comprising the steps of:

installing a rod or stem having a first end positioned within the intramedullary canal and a second end that remains exposed;

coupling a referencing fixture to the second end of the rod or stem;

measuring the extent of the lateral femoral condyle or trochlear region using the referencing fixture; and

resecting the distal femur in accordance with the extent of the lateral femoral condyle or trochlear region, as measured with the referencing fixture.

6. The method of claim 5, including the step of placing a spacer between the referencing fixture and the lateral femoral condyle or trochlear region.

7. When installing a prosthesis onto a distal femur having a trochlear region, an improvement to promote restoration with respect to the patellar femoral joint in the distal plane, comprising:

increasing the depth of the trochlea with increasing implant size so as to optimize the patella femoral mechanics.

8. A method of resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region, the method comprising the steps of:

a) installing a fixture onto the distal femur which references the non-prominent condyle or trochlear region; and

b) resecting the femur in accordance with the reference made in (a).

9. The method of claim 8, wherein the step of installing a fixture onto the distal femur includes the step of:

placing an intramedullary rod in the distal femur having a movable guide; and

moving the guide until the guide touches the non-prominent condyle or trochlear region.

10. The method of claim 8, wherein:

the femur has a longitudinal axis; and

the resection is substantially transverse to the longitudinal axis.

11. The method of claim 8, wherein the resection is a distal cut.

12. Apparatus for resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region, comprising:

a fixture including a movable member which references one of the non-prominent and trochlear regions; and

a cutting guide to resect the femur in accordance with the reference made using the fixture.

13. The apparatus of claim 12, wherein the fixture further includes:

an intramedullary rod; and

a reference guide movable on the rod.

14. The apparatus of claim 13, wherein the fixture further includes a medial-to-lateral slide to which the reference guide attaches, enabling either condyle or the trochlear region to be used as a reference for subsequent resection.

15. The apparatus of claim 12, further including a prosthesis installable on the distal femur in accordance with the resection made with the cutting guide.

Abstract of the Disclosure

In knee-replacement surgery, restoration is achieved with respect to the patellar femoral joint in the distal plane is, thereby optimizing patellar femoral mechanics. The depth of the trochlea is increased with increasing implant size. In the preferred embodiment, this is achieved by referencing the extent of the lateral femoral condyle or trochlear region, and resecting the distal femur in accordance with the extent of the lateral femoral condyle or trochlear region. As an alternative, the invention provides for distal femoral and proximal tibial components having bone-contacting and articulating surfaces which account for the measured extent of the lateral femoral condyle or trochlear region. A method of preparing a distal femur according to the invention includes the steps of installing a rod or stem within the intramedullary canal, and attaching a referencing fixture thereto. The extent of the lateral femoral condyle or trochlear region is measured using the referencing fixture, and the distal femur is resected in accordance with the extent of the lateral femoral condyle or trochlear region. The method typically further includes the step of placing a spacer between the referencing fixture and the lateral femoral condyle or trochlear region. The preferred alternative embodiment of the invention involving the use of modified components proceeds similarly, except that after measuring the extent of the lateral femoral condyle or trochlear region using the referencing fixture, distal femoral and proximal tibial components are implanted having bone-contacting and articulating surfaces which take the measurement into account.

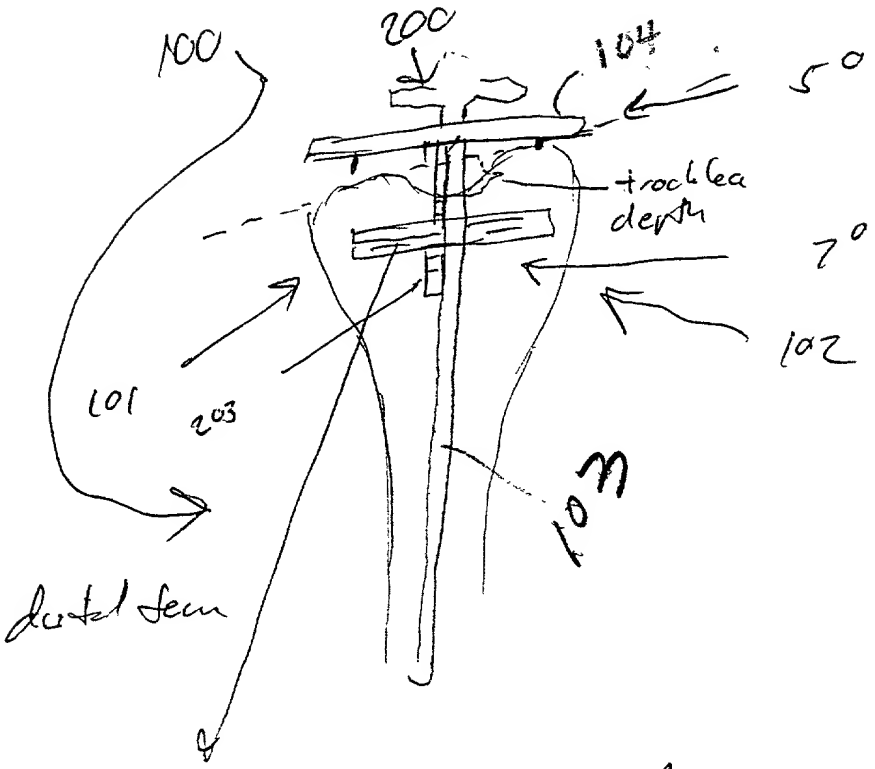
100
200
104
50
trochlea depth
70
102
101
203
103
distal femur
distal cutting guide
202

Fig-1

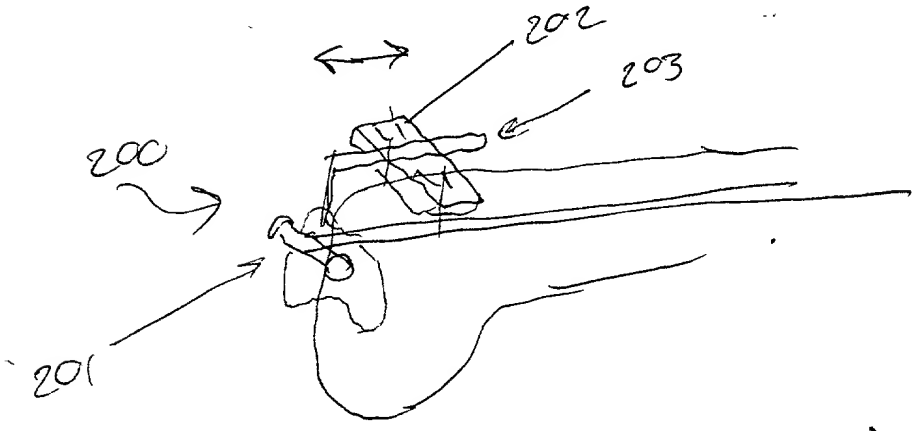
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Fig-2

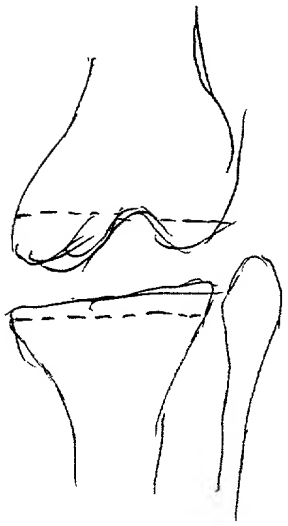


Fig-3A

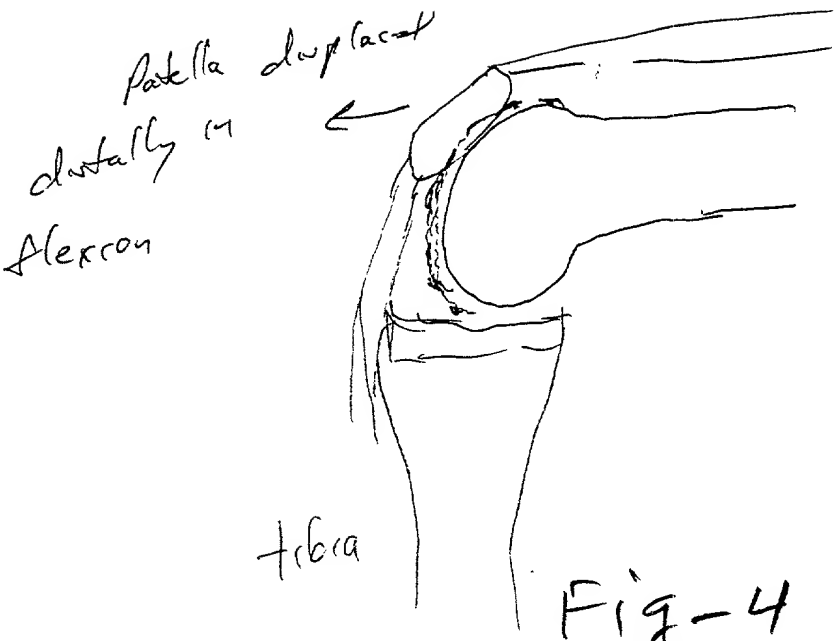


Fig-4

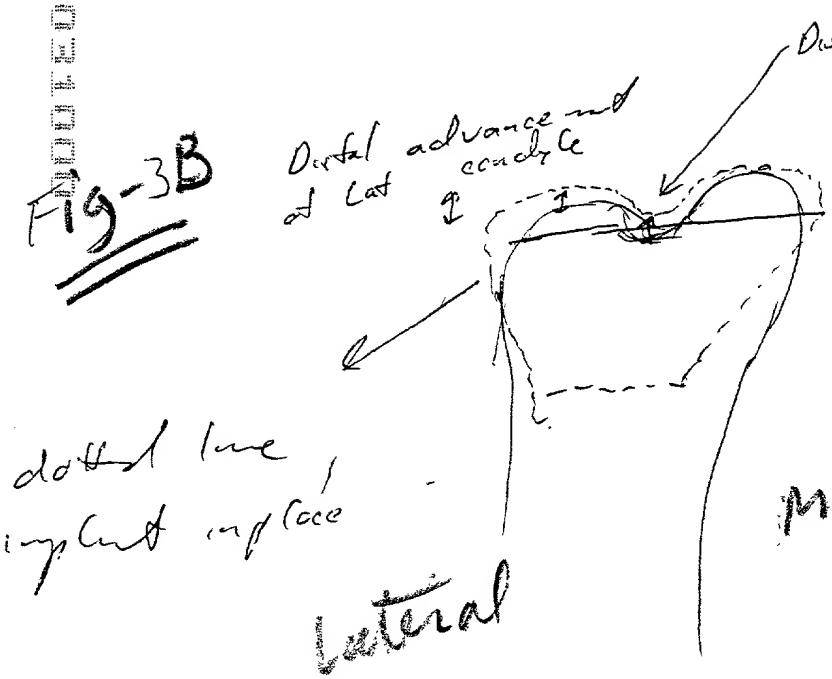


Fig-3B

(Asymmetric distal resection
- remove less laterally

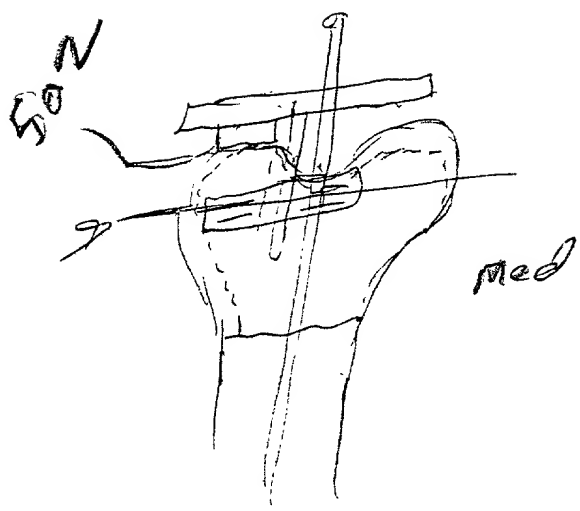


Fig-5

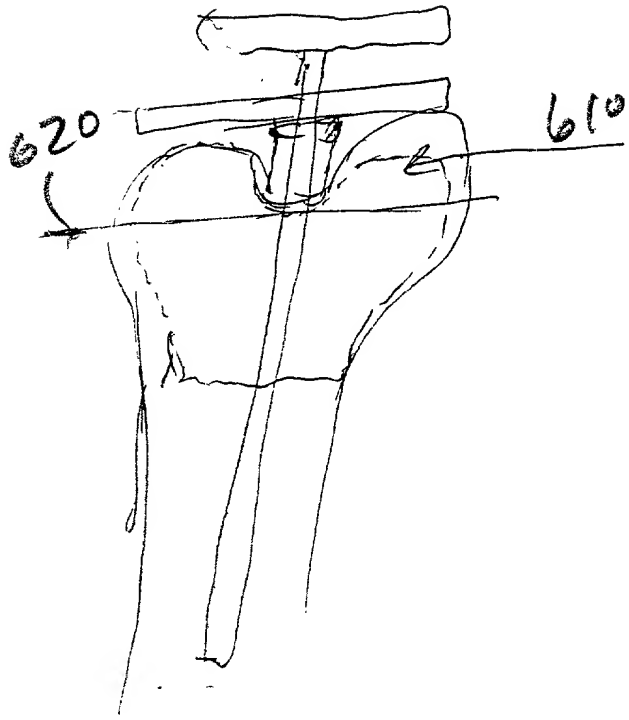


Fig-6

Fig 7 "Anatomic" cpt cond

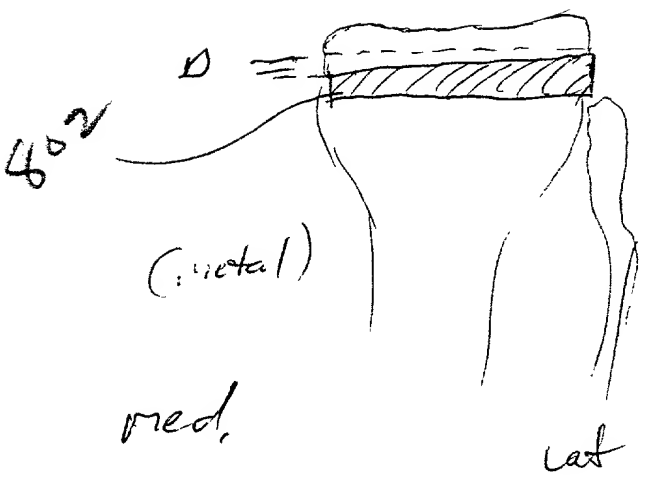


Fig-8A

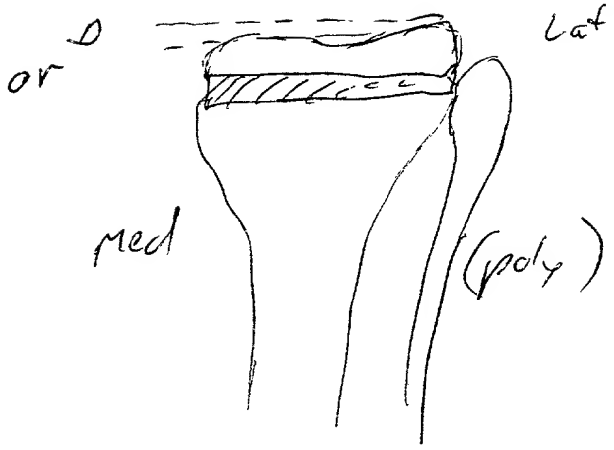


Fig-8B

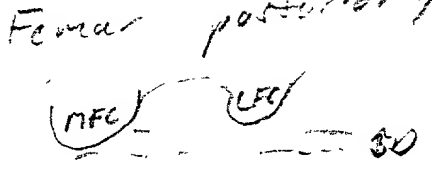


Fig-8C

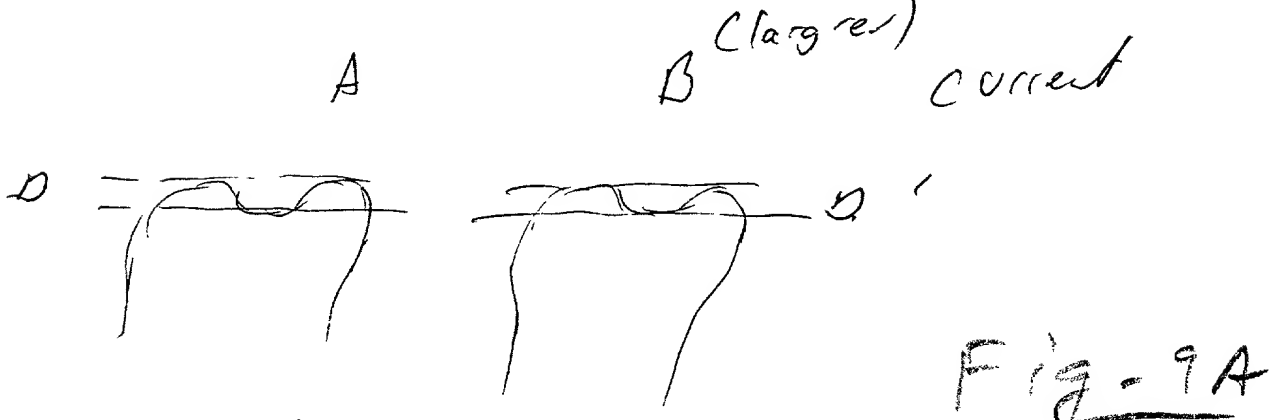
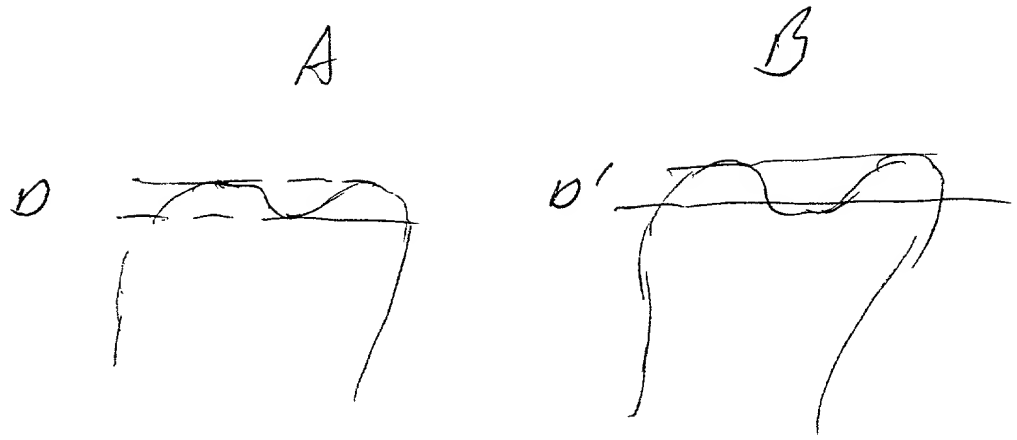


Fig-9A

D = D' currently



D' is bigger than D with each increase in size.

Fig-9B

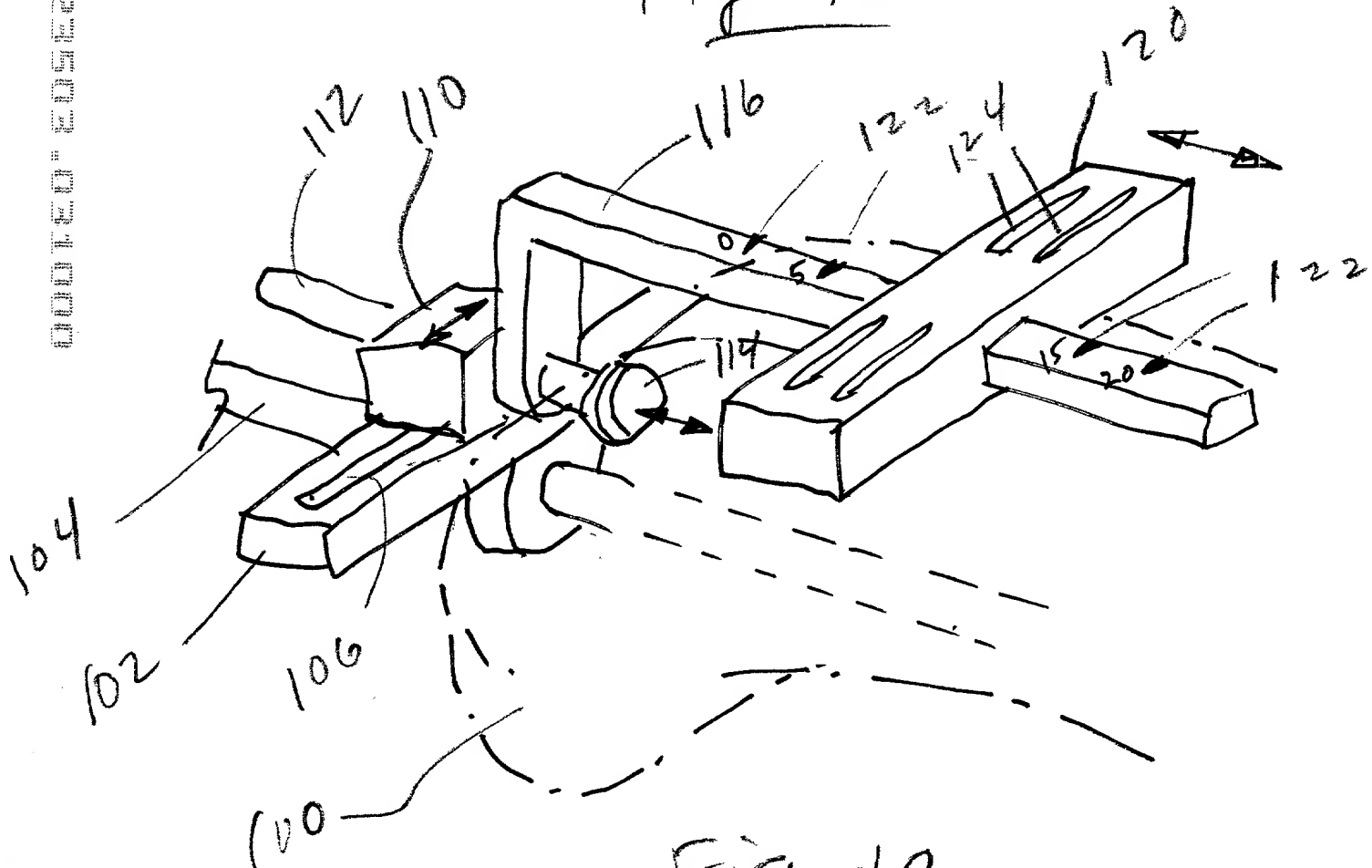


Fig-10

Attorney's Docket No.: MED-02702/29

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As the below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is the following type:

- ■ original
- ☐ design
- ☐ supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part do not check next item, check appropriate one of last three items

- ☐ national stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP

- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted

My resident, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

OPTIMIZING PATELLAR FEMORAL MECHANICS
THROUGH ALTERNATIVE DEPTH REFERENCING

SPECIFICATION IDENTIFICATION

the specification of which: *(complete (a), (b) or (c))*

(a) ■ is attached hereto.

(b) ☐ was filed on _____ as ☐ Serial No. 0 /_____ or ☐ Express Mail No., *as Serial No. not yet known* _____ and was amended on _____ *(if applicable).*

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67

(c) ☐ was described and claimed in PCT International Application No. _____ filed on _____ and as amended under PCT Article 19 on _____ *(if any)*.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge to the duty to disclose information

■ which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

(also check the following items, if desired)

☐ and which is material to the patentability of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ■ no such applications have been filed.
(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check Item (e), enter the details below and make the priority claim.

A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119

Country (or indicate if PCT)	Application Number	Date of Filing (day, month, year)	Priority Claimed Under 37 USC 119
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
60/120,062	March 12, 1999

POWER OF ATTORNEY

I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Ernest I. Gifford (Reg. No. 20,644)
Allen M. Krass (Reg. No. 18,277)
Irvin L. Groh (Reg. No. 17,505)
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full name of sole inventor MICHAEL A. MASINI

Inventor's signature _____

Date 3/8/00 Country of Citizenship US

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CHECK PROPER BOX(ES) FOR ANY OF THE FOLLOWING ADDED PAGE(S) WHICH FORM A PART OF THIS DECLARATION

☐ Signature for third and subsequent joint inventors. *Number of pages added* _____.

* * *

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____.

* * *

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____.

* * *

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (CIP) application. *Number of pages added* _____.

* * *

☐ Authorization of attorney(s) to accept and follow instructions from representative.

* * *

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item

■ This declaration ends with this page.